



CERTIFICATE OF ANALYSIS
GemCell™ Human Serum AB
(Catalog Number 100-512)Heat Inactivated*

Lot Number: H42X00K

Date of Manufacture: Apr2019

Origin: United States

Product Expiry: Apr2024

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

Storage Temperature: ≤ -10°C

Product description: GemCell™ human serum AB is collected from healthy male donors of the AB serotype at FDA-licensed facilities located in the United States. Donor units are tested for infectious disease markers prior to processing and found to be non-reactive. Gemcell™ is converted to serum from human plasma using bovine thrombin and sterile-filtered through a 0.1 µm filter prior to freeze.

| Test | Methodology | Specification | Analysis |
|--------------------------------|-----------------------------------------|--------------------|--------------|
| Biological Testing | | | |
| Endotoxin | USP<85>, EP 2.6.14 | < 10.0 EU/ mL | <0.500 EU/mL |
| Hemoglobin | Fleming, AF and Woolf, AJ (1985) | <20.0 mg/ dL | 7.3 mg/dL |
| Microbiological Testing | | | |
| Sterility | USP<71>, EP 2.6.1 | | |
| Bacteria | | No Growth | No Growth |
| Fungi | | No Growth | No Growth |
| Mycoplasma | Barile, MF and Kern, J (1971), EP 2.6.7 | Not Detected | Not Detected |
| Viral Testing | | | |
| HBsAg | 21CFR 610.40 ABBOTT ChLIA | Non-Reactive | Non-Reactive |
| Anti-HCV | ABBOTT ChLIA | Non-Reactive | Non-Reactive |
| Anti-HIV-1/ HIV-2 | ABBOTT ChLIA | Non-Reactive | Non-Reactive |
| Syphilis | ASI RPR | Negative | Negative |
| HBV-NAT | ROCHE NAT/ PCR | Not Detected | Not Detected |
| HIV-NAT | ROCHE NAT/ PCR | Not Detected | Not Detected |
| HCV-NAT | ROCHE NAT/ PCR | Not Detected | Not Detected |
| Physical Testing | | | |
| Osmolality | USP<785>, EP 2.2.35 | 260 – 350 mOsm/ kg | 313 mOsm/kg |
| pH | USP<791> | Test and Report | 8.0 |
| Biochemistry | | | |
| Albumin | | Test and Report | 3.2 |
| ALT (SGPT) | | Test and Report | 13 |
| AST (SGOT) | | Test and Report | 14 |
| Bilirubin, Total | | Test and Report | 0.2 |



| Test | Methodology | Specification | Analysis |
|----------------|-------------|-----------------|----------|
| BUN | | Test and Report | 13 |
| Calcium | | Test and Report | >3.75 |
| Chloride | | Test and Report | 109 |
| Cholesterol | | Test and Report | 126 |
| Creatinine | | Test and Report | 0.78 |
| Glucose | | Test and Report | 5.4 |
| Phosphorus | | Test and Report | 1.0 |
| Potassium | | Test and Report | 3.8 |
| Protein, Total | Biuret | Test and Report | 5.3 |
| Sodium | | Test and Report | >165 |
| Triglycerides | | Test and Report | 70 |
| Uric Acid | | Test and Report | 2.9 |

All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. This product is a pool of > 100 donor units and the viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. The bovine thrombin that is used as part of the conversion to serum is sourced from controlled herds located in the United States and the source cattle are ante and post-mortem inspected by a U.S. Veterinary Service Inspector where they were deemed free of infectious and contagious diseases. All animals used in the production of the thrombin were from a natural beef program in accordance with FDA regulations. The purified thrombin undergoes a pasteurization process where it is treated at $62^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for a period of 10 hours. This pasteurization process is validated by the vendor. Material is derived from human blood and should be considered biohazardous. Universal precautions should be used when handling this material. * Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation.

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Megha Kharasi

Name

QA Associate III

Title

01 May 2020

Date